K093094

MAY 11 2010

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Manufacturing Site:	Cardinal Health 211 1100 Bird Center Drive Palm Springs, CA 92262
Contact:	Farokh Etemadieh (714) 919-3249 (phone); (714) 283-8420 (fax)
Summary Date	June 5,-2009
Device Trade Name:	VELA Ventilator
Device Common/Classification Name:	Classification name: 868.5895 Continuous Ventilator, 73 CBK
Establishment Registration Number	202171
Device Class:	Class II
Classification Panel:	Anesthesiology
Predicate Device:	The predicate devices are: • Maquet Servo-I K022132 • LTV 1200: K060647 • Cardinal Health AVEA Ventilator: K073069

Device Description:

A VELA with the CO_2 monitoring option is intended to monitor the effectiveness of ventilation. It may be used on adult and pediatric patients. It is suitable for use in a hospital critical care environment, and is a restricted medical device intend for use by qualified trained personnel under the direction of a physician.

The VELA Series Ventilator is a modified Tbird Ventilator and like its predecessor, is an easy to use, self-contained, servo-controlled, software-driven ventilator. It has a dynamic range of breathing gas delivery that provides for pediatric through adult patients. Its revolutionary user interface module provides maximum flexibility with simple operator interaction. It has a flat panel color LCD with real time charting and digital monitoring capabilities, a touch screen for easy interaction, membrane keys and a dial for changing settings and operating parameters. A precision gas delivery turbine with servo controlled active inhalation and exhalation improves performance over previous generations.

The VELA Series Ventilator may be configured as a conventional ventilator or non-invasive positive pressure ventilator (NPPV). It is easy to clean and its design does not allow liquids to pool on the casing, reducing the likelihood of fluid leakage into the body of the ventilator.

The VELA Series Ventilator base model comes with comprehensive features for the critical care environment. Optional features can be added at time of purchase or at a later date.

Intended Use:

The Vela ventilator is intended to provide continuous or intermittent ventilatory support for the care of individuals who require mechanical verification. The ventilator is a restricted medical device intended for use by qualified, trained personnel under the direction of a physician. Specifically, the ventilator is applicable for adult and pediatric patients weighing at least 5 kg (11lb), who require the following general types of ventilation support, as prescribed by attending physician:

Positive pressure ventilation
Assist/Control, SIMV, or CPAP modes of ventilation

The ventilator is suitable for use in institutional and transport settings. It is not intended for use as an emergency medical transport ventilator or for homecare applications.

Substantial Equivalence:

Predicate Device Information

The predicate device(s) are:

- Maquet Servo-I: **K022132**
- LTV 1200: **K060647**
- Cardinal Health AVEA: **K073069**

The modifications to VELA associated with this submittal as follows:

- An End Tidal CO_2 monitoring option consisting of an external mainstream CO2 sensor module, the CAPNOSTAT 5, OEMed from Respironics and for added safety connected to the device using a LEMO connector at extra safety low voltage (SELV).
- The ventilator will be applicable for adult and pediatric patients weighing at least 5 kg (11 lb), who require continuous respiratory support, as prescribed by an attending physician.
- Monitoring of f/Vt and Circuit Resistance.
  F/Vt monitoring by definition is the rapid shallow breathing index calculated by the ratio of the monitored spontaneous breath rate and monitored tidal volume. F/Vt is described at page 118 and Circuit Resistance at page 75 of the Vela operator manual L2854-101 Rev. B and exhibit A.
- The setting range of the PSV Cycle changed from 5 - 30% to 5 - 70%.

Summary of Testing and Validation:

In Summary Performance testing verified that the VELA Ventilator meets it's performance requirements and that this device is substantially equivalent to predicate medical devices currently legally marketed in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 11 2010

Mr. Farokh Etemadieh
Regulatory Affairs Consultant
Cardinal Health 207, Incorporated
22745 Savi Ranch Parkway
Yorba Linda, California 92887

Re: K093094
Trade/Device Name: Vela Ventilator
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: April 22, 2010
Received: April 27, 2010

Dear Mr. Etemadieh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) number (if known): K093094

Device Name: VELA Ventilator
Indications for Use:

The VELA Ventilator is intended to provide continuous or intermittent respiratory support in an institutional health care environment (e.g. hospitals) for individuals who require mechanical ventilation. The ventilator is a restricted medical device intended for use only by qualified trained personnel under the direction of a physician. It may be used on adult and pediatric patients. Specifically, the ventilator is applicable for adult and pediatric patients weighting at least 5 kg (11lb), who require the following types of ventilation support, as prescribed by an attending physician.

- Positive pressure ventilation
- Assist / control, SIMV, or CPAP modes of ventilation

The ventilator is suitable for use in institutional and transport settings. It is not intended of use in an emergency medical transport ventilator or for home care applications.

WARNING

The Vela ventilator is approved for institutional use only and should not be used to transport patients outside of the institutional setting.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH Office of Device Evaluation ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
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